UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Robert Kopesky et al.	:	Group Art Unit: 1609
Application No.: 10/521,886	:	Examiner: Layla D. Bland
Filed: July 5, 2005	:	Confirmation No.: 8844
For: Production of Microcrystalline Cellulose	:	

Mail Stop Appeals Brief-Patents
Director of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FILING OF AMENDED APPEAL BRIEF

In response to the Notification of Non-Compliant Appeal Brief (37 C.F. R. 41.37) dated May 21, 2008, in the above-identified application, Appellant herewith submits an amended Appeal Brief. This response is considered timely by virtue of the fact that it is being submitted within one month of the date of the Notification.

The Amended Appeal Brief corrects two typographical errors on page 4 of the brief by referring to the correct U.S. Patent no. for the Trusovs et al. reference, namely, U.S. Patent no. 6,392,034. The Amended Appeal Brief also corrects two typographical errors on page 10 of the brief by referring to the rejection of claims 1-17 under 35 U.S.C. 103(a) rather than the rejection of claims 1-7.

Favorable consideration and entry of the Amended Appeal Brief are requested.

Respectfully submitted,

Date: May 30, 2008

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Sir:

AMENDED APPEAL BRIEF

This is an appeal from the rejection set forth in the Final Rejection dated October 30, 2007, (hereinafter "the Final Rejection") in the above-identified application. Appellant respectfully submits that the rejections in the Final Rejection were made in error, and that the rejections should be reversed for the reasons set forth below.

I. The Real Party in Interest

The real party in interest in the present appeal is FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 to whom an undivided interest in the above-captioned application has been assigned by virtue of an assignment by the inventors to FMC Corporation, recorded on July 12, 2005, at reel 016248, frame 0299.

II. Related Appeals and Interferences

The Appellant is unaware of any pending appeals or interferences related to the present appeal.

III. The Status of the Claims

Claims 1-31 are currently pending in the present application and stand rejected in the Final Rejection. The rejections of claims 1-31 are hereby appealed. A copy of the currently pending claims 1-31 is attached as an appendix hereto.

IV. The Status of any Amendments Filed after Final Rejection

No amendments were filed after the Final Rejection dated October 30, 2007.

V. Summary of the Claimed Subject Matter

The invention of claim 1 is a process for producing microcrystalline cellulose (page 3, line 26 of the specification). A reaction mixture comprising a cellulose material, an active oxygen compound and water, is subjected to a high shear treatment at elevated temperature for a time effective to depolymerize the cellulose material (page 3 lines 26-30 of the specification). This is an efficient, one-step process for the production of microcrystalline cellulose. (page 3, lines 26-27 of the specification).

The applicant has found that the process of the present invention provides a significant, unexpected effect relative to conventional acid hydrolysis processes. Specifically, Example 2 and Table 2 of the present specification demonstrate that it is possible to achieve a significantly lower degree of polymerization (DP) using the process of the present invention (samples 1-5), as compared to control samples 6-11 obtained by conventional acid hydrolysis. Samples 1-5 had DP values consistently lower than comparable samples 6-11 made by conventional acid hydrolysis. Lower degrees of polymerization are important for obtaining regulatory approval. See page 8, line 26 to page 9, line 1 of the specification). Thus, the present invention may permit otherwise unsuitable starting materials to be depolymerized to levels sufficient to meet regulatory requirements.

The invention of claim 9 is a process as claimed in claim 1 wherein the active oxygen compound is hydrogen peroxide (page 5, lines 19-20 of the specification) and the reaction mixture is subjected to the high shear treatment in an extruder system including a barrel and a product outlet (page 6, line 23 to page 7 line 12 of the specification). The hydrogen peroxide comprises an aqueous solution (page 5, lines 19-20 of the specification) and is admixed with the cellulose material prior to introduction of the cellulose material to the extruder system (page 7, lines 14-18 of the specification).

The invention of claim 10 is a process as claimed in claim 1 wherein the active oxygen compound is hydrogen peroxide (page 5, lines 19-20 of the specification) and

the reaction mixture is subjected to the high shear treatment in an extruder system including a barrel and a product outlet (page 6, line 23 to page 7 line 12 of the specification). The hydrogen peroxide comprises an aqueous solution (page 5, lines 19-20 of the specification) and is introduced into the extruder system after introduction of the cellulose material (page 7, lines 14-18 of the specification).

The invention of claim 14 is a process as claimed in claim 1 wherein the active oxygen compound is hydrogen peroxide (page 5, lines 19-20 of the specification) and the reaction mixture is subjected to the high shear treatment in an extruder system including a barrel and a product outlet (page 6, line 23 to page 7 line 12 of the specification). In the process of claim 14, the extrusion system comprises a twin screw extruder (page 7, lines 3-12 of the specification), the cellulose material comprises about 30% to about 50% by weight of the reaction mixture (page 7, line 31 of the specification), and the hydrogen peroxide comprises about 0.1% to about 10% by weight of the reaction mixture, on a 100% active basis of hydrogen peroxide (page 7, lines 23-28 of the specification).

The invention of claim 16 is the process of claim 14 wherein the extrusion is continuous and residence time is 15 minutes or less (page 8, lines 14-16 of the specification).

The invention of claim 17 is the process of claim 14 wherein the extrusion is continuous and residence time is 5 minutes or less (page 8, lines 14-16 of the specification.

VI. Grounds of Rejection to be Reviewed on Appeal

Appellant believes that there are three grounds of rejection to be reviewed on appeal. These grounds of rejection may be concisely summarized as follows:

1. Claims 4-7 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention, based on inclusion of the term, "at least about" in these claims.

2. Claims 1-17, 20, 22-24, 26 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent no. 6,228, 213 B1 (Hanna, et al.) in view of International patent application publication no. WO 01/05441 A1 (Schaible, et al.) and U.S. Patent no. 6,392,034 B1 (Trusovs, et al.).

3. Claims 18-21, 25-27 and 29-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent no. 6,228, 213 B1 (Hanna, et al.) in view of International patent application publication no. WO 01/05441 A1 (Schaible, et al.) and U.S. Patent no. 6,392,034 B1 (Trusovs, et al.) and further in view of U.S. Patent no. 5,192,569 (McGinley, et al.).

VII. Argument

1. The Rejection of Claims 4-7 Under 35 U.S.C. §112, Second Paragraph

Claims 4-7 have been rejected under 35 U.S.C. §112, second paragraph, on the basis that the term, "at least about" is a relative term that renders the scope of these claims indefinite. Claim 4 illustrates the use of the term, "at least about" in the context of claims 4-7 of the present application:

> Claim 4. The process of claim 3 wherein the elevated temperature during the high shear treatment is at least about 40°C as measured on the barrel.

MPEP §2173.05(b) explains that when determining indefiniteness,

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Thus, use of relative terminology does not automatically render the claim indefinite. Accordingly, since the Examiner bears the burden of presenting a *prima* facie rejection, the Examiner must not only demonstrate that relative terminology has been employed in the claim, but also must justify why, in the context of the present claims 4-7, the term, "at least about" renders the claim indefinite. The only basis provided by the Examiner in support of the rejection is the Examiner's statement that, "The term ['at least

about'] is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." Final Rejection, p. 3, lines 2-3.

35 U.S.C. 112 does not require that terms used in a claim be defined by the claim itself. Thus, this basis for the Examiner's rejection is not a legitimate statutory basis and should therefore be disregarded.

The Examiner also bases this rejection on a statement that the specification does not provide a standard for ascertaining the meaning of the term, "at least about." Again, 35 U.S.C. 112 does not require that terms used in a claim be defined the specification. Thus, this unsupported allegation of the Examiner, taken alone, does not make out a *prima facie* case of indefiniteness.

Finally, the Examiner makes the conclusory statement that a one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. However, The Examiner has presented no evidence on the issue of whether a person of ordinary skill in the art would understand what is claimed, in light of the specification and offers no reasoning in support of this statement, other than the fact that the term, "at least about" is not clearly defined in the specification or claim, as discussed above. Accordingly, since the only justification offered by the Examiner in support of the rejection, i.e. the lack of an express definition in the claim or specification, is not required by the statute, and the Examiner has offered no evidence whatsoever in support of the rejection, the Examiner has failed to make out a *prima facie* case of indefiniteness.

In actual fact, the evidence of record supports the applicant's position that the term "at least about" as it is used in the context of claims 4-7 of the present application is sufficiently definite to meet the requirements of 35 U.S.C. §112. For example, the specification of the present application provides a skilled person with information on the meaning of the terminology "at least about."

Specifically, page 8, line 4 of the specification indicates that the reaction mixture will heat to "at least about 40°C." Page 8, line 12 of the specification gives a preferred temperature range of "about 50 to 110°C." A skilled person familiar with the English language would conclude that the statement, "At least about 40°C" must mean something different from the statement "about 50°C" or "about 50°C" would not have been

separately mentioned in the specification as a preferred embodiment of "at least about 40°C". From this, a skilled person could draw the conclusion that the specification indicates that "about", as used in this context, means, at most, ± 5°C since otherwise the statement "about 40°C" would overlap with the statement "about 50°C".

The Examiner erroneously disregards this information presented in the present specification on the basis that, "A preferred example is not a clear definition." See Final Rejection, p. 3, l. 10. First, as discussed above, 35 U.S.C. §112 does not require that the specification provide a clear definition of a term, but only that the term can be interpreted with a reasonable degree of particularity by a person of ordinary skill in the art. Thus, the Examiner's rationale is again, unsupported by the statute. The Examiner has presented no evidence on the issue of whether a person of ordinary skill in the art would understand what is claimed, in light of the specification.

The Examiner has also asserted that the decision in *Amgen, Inc. v. Chugai*, 927 F.2d 1200, 1218, 18 USPQ2d 1016 (Fed. Cir. 1991) mandates a determination that the term "at least about" is indefinite as used in the context of claims 4-7 of the present application. First, it should be noted that this particular court decision, relied on by the Examiner, was clearly a highly exceptional case. For example, 68,946 United States patents have issued since 1976 employing the phrase "at least about" in the claims showing that in at least 68,946 circumstances since 1976, this terminology satisfied 35 U.S.C. 112. Also, two other court decisions, *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446, 7 USPQ2d 1191, 11999 (Fed. Cir. 1988) ("at least about") and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 842 F.2d 1275, 6 USPQ2d 1277 (Fed. Cir. 1988) ("exceeding about") held that essentially the same claim terminology satisfied 35 U.S.C. 112. This evidence shows that the decision relied on by the Examiner, *Amgen, Inc. v. Chugai*, cited infra, is a highly exceptional case which was based on a very specific fact situation. The specific fact situation of *Amgen, Inc. v. Chugai*, cited infra is not applicable to the present case as discussed in detail below.

Initially, the *Amgen, Inc. v. Chugai* decision referenced *W.L. Gore & Associates*, indicating that,

> In arriving at this conclusion, we caution that our holding that the term "about" renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims. It may be acceptable in appropriate fact

> situations, *e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 U.S.P.Q. (BNA) 303, 316 (Fed. Cir. 1983) ("use of 'stretching . . . at a rate exceeding about 10% per second' in the claims is not indefinite"), even though it is not here.

927 F.2d at 1218. Thus, the *Amgen, Inc. v. Chugai* decision cautioned that it should not rule out any and all uses of the term, "about" in patent claims. Rather, *Amgen, Inc. v. Chugai* makes it clear that it is important to consider the specific factual situation of each case rather than applying a blanket rule. The Examiner in the present case has not given due consideration to the specific facts of the case and thus has erroneously concluded that the term, "at least about" as used in the context of claims 4-7 of the present application is indefinite.

More specifically, the present case is not an exceptional case as in *Amgen, Inc. v. Chugai* since the facts of *Amgen, Inc. v. Chugai* were significantly different from the facts of the present case. For example, *Amgen, Inc. v. Chugai* stated that,

> The court found the "addition of the word 'about' seems to constitute an effort to recapture . . . a mean activity somewhere between 120,000, which the patent examiner found was anticipated by the prior art, and [the] 160,000 IU/AU" claims which were previously allowed. Because "the term 'about' 160,000 gives no hint as to which mean value between the Miyake et al. value of 128,620 and the mean specific activity level of 160,000 constitutes infringement," the court held the "at least about" claims to be invalid for indefiniteness. 13 U.S.P.Q.2d at 1787-88.

927 F.2d at 1218. In the present case, the term "at least about" was not added by amendment and there has been no effort to recapture subject matter using this terminology. Thus, one of the two primary rationales for the holding in *Amgen, Inc. v. Chugai*, namely, the addition of the term by amendment in an apparent attempt to recapture subject matter between the scope of previously allowed claims and the prior art, has not occurred in the present case.

As a second justification for its holding, the court in *Amgen, Inc. v. Chugai* said,

> This holding was further supported by the fact that nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term "about," and by the fact that no expert testified as to a definite meaning for the term in the context of the prior art.

927 F.2d at 1218. As discussed above, the present specification provides an indication as to what range of temperature is covered by the term, "at least about", contrary to the situation in *Amgen, Inc. v. Chugai* and thus the present case is clearly distinguishable from *Amgen, Inc. v. Chugai* for this reason as well.

Finally, in *Amgen, Inc. v. Chugai* there was prior art cited against the claim at issue that met every limitation of that claim except the limitation containing the term "at least about." In the present case, the Examiner admits that Hanna et al. completely lacks a teaching of a process for producing microcrystalline cellulose using an active oxygen compound (Final Rejection, p. 5, lines 7-8). Thus, at least one limitation of claims 4-7 of the present application which distinguishes these claims from the primary reference to Hanna et al. is not the limitation containing "at least about" as it was in *Amgen, Inc. v. Chugai*, but instead is a different claim limitation.

Accordingly, it is clear that none of the important facts of *Amgen, Inc. v. Chugai* offered in support of the holding of indefiniteness applies to the present application. This makes it absolutely clear that the exceptional decision in *Amgen, Inc. v. Chugai* does not apply to the present case. In summary, the present situation differs from the facts of *Amgen, Inc. v. Chugai* in two additional important respects:

(1) the prior art situation in the present case is not comparable to the situation that existed in *Amgen, Inc. v. Chugai*, since a limitation of claims 4-7 which does not include the "at least about" language is completely missing from the primary reference relied on by the Examiner, namely, Hanna, et al.,

(2) the "at least about" limitation is not relied on in the present case to distinguish from the closest prior art reference to Hanna et al., as was the situation relative to the Miyake et al. reference in *Amgen, Inc. v. Chugai*,

(3) the specification of the present application contains information that can be used by a skilled person to determine the meaning of the term, "at least about" whereas the specification in *Amgen, Inc. v. Chugai* did not contain any information relevant to this inquiry, and

(4) the "at least about" limitation of the present claims 4-7 was not added by amendment in an attempt to recapture subject matter as was the situation in *Amgen, Inc. v. Chugai*.

Accordingly, to sum up, the rejection of claims 4-7 under 35 U.S.C. §112, second paragraph, should be withdrawn for at least the following reasons:

(1) the specification provides guidance as to the meaning of the term, "at least about",

(2) *Amgen, Inc. v. Chugai* does not hold that the term, "at least about" is indefinite in all cases but rather only under one set of exceptional circumstances which does not apply to the present case,

(3) at least two other decisions of the Federal Circuit interpreting the same or similar terminology "at least about" or "exceeding about" did not find these terms to be indefinite,

(4) the facts of the present situation differ in at least four very significant respects relied on by the court in its decision in *Amgen, Inc. v. Chugai*, as discussed above, and

(5) 68,946 U.S. patents have issued since 1976 employing the phrase "at least about" in one or more claims thereby demonstrating that in at least 68,946 circumstances this terminology has been found to be definite by the U.S. Patent and Trademark Office and confirming the applicant's position that the decision in *Amgen, Inc. v. Chugai* was exceptional.

The Examiner has elected to ignore the fact that 68,946 U.S. patents have issued since 1976 employing the terminology "at least about" in at least one claim on the basis that "patents are property and not available as precedent." However, contrary to the Examiner's assertion the applicant has not cited these 68,946 patents as precedent. Rather, the applicant has cited these patents as evidence that 68,946 times, when faced with the terminology "at least about" the U.S. Patent and Trademark Office has found it to be definite. This provides overwhelming evidence that this term should be considered definite absent extremely exceptional circumstances to the contrary, such as the exceptional circumstances that were present in *Amgen, Inc. v. Chugai* and which are not present in this case. The Examiner has presented no evidence or arguments justifying that the present situation is an extremely exceptional circumstance which mandates that the U.S. Patent and Trademark Office reach a different conclusion on indefiniteness than was reached in 68,946 previously issued patents, all of which are presumed to be valid

under 35 U.S.C. 282 and thus are also presumed to meet the requirements of 35 U.S.C. §112.

Accordingly, the Examiner has not met her burden of establishing a *prima facie* case of indefiniteness and the rejection of claims 4-7 should be reversed. Favorable consideration and reversal of the rejection of claims 4-7 under 35 U.S.C. §112 is requested.

2. The Rejection of Claims 1-17, 20, 22-24, 26 and 28 Under 35 U.S.C. §103(a)

Claims 1-17, 20, 22-24, 26 and 28 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Pat. no. 6,228,232 B1 (Hanna), in view of WO 01/02441 A1 (Schaible) and U.S. Pat. no. 6,392,034 B1 (Trusovs).

The primary reference relied on by the Examiner, namely, Hanna et al. discloses a process for producing microcrystalline cellulose by subjecting a reaction mixture of cellulose material, water and acid to reactive extrusion at an extruder barrel temperature of 80-200°C. See col. 3, lines 30-65 of Hanna et al.). The Examiner admits that Hanna et al. does not disclose using an active oxygen compound (Final Rejection, p. 5, lines 7-8) in its second process step wherein microcrystalline cellulose is produced from cellulose.

The secondary reference to Schaible et al. teaches a process for producing microcrystalline cellulose by hydrolyzing cellulosic pulp with active oxygen in an acidic environment to both bleach and hydrolyze the pulp in a one-step process. (See page 5, lines 1-4 of Schaible et al.). The starting material of Schaible et al. is simultaneously hydrolyzed and bleached to obtain a microcrystalline cellulose product. (page 2, lines 20-24 of Schaible et al.).

Trusovs teaches a method of producing microcrystalline cellulose by treating cellulose with an alkaline solution at 20-100°C to form an alkaline suspension and subsequently de-polymerizing the cellulose material with peroxide. See col. 2, lines 18-21 of Trusovs.

A. Claim 1

i. Motivation to Combine

The Examiner concludes that it would have been obvious to use the reactive extrusion process of Hanna et al. with hydrogen peroxide to produce microcrystalline cellulose (Final Rejection, p. 5, lines 4-6) in view of Schaible or Trusovs. The Examiner alleges two motivations to combine the teachings of the cited references:

(1) it would be obvious to modify Schaible to employ the extruder method of Hanna to achieve a shorter reaction time, and

(2) it would be obvious to use the hydrogen peroxide of Schaible or Trusovs for hydrolysis since it also bleaches the material at the same time and thus, according to the Examiner, there would be no need for a separate bleaching step if this were done.

With respect to the Examiner's alleged motivation (1), Hanna et al. teaches that the extruder method has a shorter reaction time than conventional batch processes for acid hydrolysis of cellulose (col. 1, lines 33-40 and col. 2, lines 5-20 of Hanna et al.), but does not disclose the reaction time of the microcrystalline cellulose production step of its process. Thus, all that is known from Hanna et al. is that relative to a batch acid hydrolysis process, the acid hydrolysis method of Hanna et al. has a shorter reaction time. Neither Schaible et al. nor Trusovs relate to the conventional batch process for acid hydrolysis of cellulose referred to in Hanna et al. Thus, the skilled person cannot determine from Hanna et al. whether the extruder method of Hanna et al. would produce a shorter reaction time than is needed for the either of the processes disclosed in Schaible et al. or Trusovs. This is because Hanna et al. does not disclose its reaction time, and because neither Schaible et al. nor Trusovs relate to the conventional batch acid hydrolysis processes to which Hanna et al. compares its reaction time.

Accordingly, obtaining a reduction in reaction time cannot be a motivation for a skilled person to modify Schaible et al. since the Examiner's alleged reduction in reaction time is pure speculation. Specifically, there is no basis in the cited references from which a skilled person can conclude that modification of the Schaible et al. process

by employing an extruder would reduce the reaction time of the Schaible et al. process. Also, the Examiner has cited no specific facts in support of her allegation that the reaction time would be reduced by this change.

The Examiner takes the position that, "The skilled artisan would interpret this teaching [of Hanna et al.] to mean that acid hydrolysis at high temperature and high shear forces is faster than acid hydrolysis without high temperature and high shear forces. The skilled artisan could easily apply this logic to the reaction with active oxygen." See page 8, last line to page 9, line 3 of Hanna et al. However, the actual facts contradict the Examiner's position.

The method of Schaible et al. differs significantly from the conventional batch acid hydrolysis processes to which Hanna et al. compares its reaction time for several reasons, including: (1) the Schaible et al. process is not a conventional batch acid hydrolysis reaction, (2) Schaible et al. already operates at high temperature, and (3) Schaible et al. employs an active oxygen compound for simultaneous depolymerization and bleaching.

The Schaible et al. reaction is already performed at high temperature (e.g. 100°C) (p. 7, lines 20-22 and the examples of Schaible et al.). Therefore, use of the extruder method of Hanna et al. would not necessarily raise the temperature already employed by Schaible et al., as the Examiner assumes. Hanna et al. specifies that the temperature during the acid hydrolysis step should be 80-200°C on the extruder barrel (col. 3, lines 60-63), which encompasses 100°C as used in Schaible et al. Thus, use of the extruder method of Hanna et al. may actually result in a reduction of the reaction temperature (e.g. from 100°C of Schaible to the 80°C on the extruder barrel of Hanna et al.) rather than increase in reaction temperature as the Examiner assumes.

Hanna et al. nowhere teaches that increasing pressure will decrease reaction time. All of the reactions in Hanna et al. are run at the same pressure. Based on the available information, it is quite plausible that use of a high temperature is solely responsible for the reduction in reaction time described in Hanna et al. and that changes in pressure do not even affect the reaction time. Clearly, Hanna et al. does not support a conclusion that increased pressure would reduce the reaction time of the method of either Schaible et al. or Trusovs.

Although Hanna et al. teaches that use of high shear forces applied by the extruder may reduce the reaction time of an acid hydrolysis process, Hanna et al. does not indicate that high shear forces would provide any benefit in a combined depolymerization and bleaching step using an active oxygen compound as taught by Schaible et al. Rather, from the combined teachings of the cited references, it is not known what effect, if any, use of an extruder in the process of Schaible et al. would have.

Schaible et al. itself sheds some light on this subject on page 7, lines 18-23, where Schaible et al. indicates that its reaction can be optimized by performing the reaction under heated temperatures. Schaible et al. also teaches that its reaction can optionally be performed under increased pressure in the same paragraph, but then states that a skilled person would have to determine the optimum conditions. The key point being that increasing temperature optimizes the reaction of Schaible et al., but that no such statement is made regarding increasing pressure.

Further, the Examiner's allegation that a skilled artisan could easily apply the logic of Hanna et al. relating to a conventional acid hydrolysis process, to the reaction with active oxygen, is unsupported by evidence and thus is pure speculation by the Examiner. This conclusion is based on the underlying assumption that the acid hydrolysis process of Hanna et al. is interchangeable with the active oxygen reaction of Schaible et al. However, this underlying assumption is incorrect.

Hanna et al. employs acid hydrolysis to de-polymerize wood pulp by cleaving the cellulose chains in the amorphous regions but leaving crystallites hydrogen bonded to each other. This is not the chemical equivalent of treatment with an active oxygen compound as in Schaible et al. The present specification teaches that treatment with an active oxygen compound provides different effects on the cellulose that appear to be independent of acid hydrolysis. See e.g. page 9, lines 10-16 of the specification. Trusovs also teaches that treatment with peroxide causes some oxidation of the cellulose to occur. See col. 2, lines 49-53 of Trusovs. A skilled person would therefore not consider an active oxygen treatment as in Schaible et al. to be interchangeable with the acid hydrolysis step of Hanna et al. since active oxygen treatment results in a different chemical reaction than acid hydrolysis, namely, oxidation. Accordingly, since the

chemistry of the reactions is different, the reaction kinetics and thermodynamics would be expected to be different. As a result, the effect of using an extruder in the reaction of Schaible et al. cannot be predicted by a skilled person as the Examiner suggests.

The Examiner's alleged motivation (2) for combining the references, namely, to avoid the need for a subsequent bleaching step also appears to contradict the actual teachings of the references. First, some of the starting materials contemplated for use by Hanna et al. (e.g. pure cellulose) do not even require bleaching. Thus, if pure cellulose were the starting material, the Examiner's alleged motivation (2) for combining the references would not apply since there would already be no need for a separate bleaching step and thus, in this circumstance, there would be no reason to use hydrogen peroxide for bleaching. The Examiner concedes that the need for bleaching is dependent on the starting material used at p. 9, lines 4-7 of the Final Rejection.

The Examiner speculates that in instances where a bleaching step will be required, the subsequent bleaching step of Hanna et al. can be eliminated by combining the extruder method of Hanna et al. with the method of Schaible et al. However, the Examiner cites no basis in the cited references in support of this conclusion. In actual fact, a close review of the teachings of Schaible et al. leads to the opposite conclusion, namely, that in nearly all cases, a subsequent bleaching step will still be required even if an active oxygen compound is employed as in Schaible et al.

Specifically, Schaible et al. compares its products to the color lightness of two commercially available microcrystalline cellulose products, namely, Emcocel® 50M and Emcocel® 90M in Table 1 of Example 1 on page 8. These commercial products had lightness values (L*) of 98.3 and 97.87, respectively. Examples 1-7, 9-10 and 12-15 and 17 of Schaible et al. all employed an active oxygen compound in the depolymerization step, yet, of these examples, only Example 1 of Schaible et al. actually achieved a lightness value equal to or greater than the commercial microcrystalline cellulose products which Schaible et al. uses as a comparative standard. All of the remaining examples 2-7, 9-10 and 12-15 and 17 of Schaible et al. resulted in lightness values (L*) inferior to the lightness values of the commercially available microcrystalline cellulose products. From this, a skilled person would conclude that in nearly all circumstances, an additional bleaching step would be required after the depolymerization process of

Schaible et al. in order to provide products having lightness values comparable to the existing commercially available microcrystalline cellulose products which Schaible et al. employs as a reference standard. Accordingly, from the teachings of Schaible et al., there is no reasonable expectation of successfully eliminating the subsequent bleaching step by using active oxygen as the Examiner suggests. Thus, the second motivation relied on by the Examiner also fails.

The Examiner also argues that there is a reasonable expectation of successfully eliminating a subsequent bleaching step based solely on the fact that Schaible et al. discloses that its active oxygen step both hydrolyzes and bleaches the material. However, considering the teachings of Schaible et al., as discussed above, there is no reasonable expectation of eliminating a subsequent bleaching step, as the Examiner suggests. Though Schaible et al. does create a reasonable expectation that some bleaching will occur in its active oxygen step, this alone will not motivate a skilled person to use the active oxygen step of Schaible et al. in the method of Hanna et al. since the skilled person must consider other factors, such as the expectation that the presence of active oxygen species will result in oxidation reactions producing some different end products than are produced by the acid hydrolysis of Hanna et al., as discussed in greater detail below.

With regard to the possible substitution of the active oxygen depolymerization process of Schaible for the acid hydrolysis of Hanna et al., the skilled person would not make such a substitution since the underlying chemical reactions are different. Specifically, as discussed above, the Hanna et al. acid hydrolysis is not the chemical equivalent of treatment with an active oxygen compound as in Schaible et al. The present specification teaches that treatment with an active oxygen compound provides different effects on the cellulose that appear to be independent of acid hydrolysis. See e.g. page 9, lines 10-16 of the specification. Trusovs also teaches that treatment with peroxide causes some oxidation of the cellulose to occur. See col. 2, lines 49-53 of Trusovs. A skilled person would therefore not consider an active oxygen treatment as in Schaible et al. to be interchangeable with the acid hydrolysis step of Hanna et al. since active oxygen treatment results in a different chemical reaction than acid hydrolysis, namely, oxidation, and thus will provide different reaction products than are obtained by acid hydrolysis. As

a result, the skilled person would expect that the properties of the microcrystalline cellulose material would be materially changed if an active oxygen treatment were substituted for an acid hydrolysis reaction.

This would lead a skilled person to conclude that the active oxygen treatment should not be substituted for, or added to, the acid hydrolysis step of Hanna et al. since the effect of the additional oxidation reaction on the properties of the resultant microcrystalline cellulose of Hanna et al. for use to make tablets (see e.g. col. 6, lines 15-22 of Hanna), would be unpredictable. A skilled person desiring to make tablets (which are subject to FDA approval) would certainly avoid implementation of steps that would produce an unknown quantity of different chemical products since the presence of such products could jeopardize the marketability of the tablet as well as its status as being FDA approved.

Trusovs entire purpose is to avoid use of an acid hydrolysis method. See e.g. col. 1, lines 34-38 and col. 2, lines 10-15 of Trusovs. A skilled person would not combine Trusovs with either Hanna et al. or Schaible et al. since both employ acid hydrolysis methods which Trusovs desires to avoid. Another object of Trusovs is to provide a method for producing microcrystalline cellulose which does not involve high temperature or high pressure (col. 2, lines 22-24 and 38-41 of Trusovs). Thus, a skilled person also would not combine Trusovs with Hanna et al. or Schaible et al. since Hanna et al. and Schaible et al. both employ and desire to use high temperatures and Hanna et al. also employs high pressure.

In the Advisory Action, the Examiner further alleges that, "...it is well known in the art that increasing temperature and pressure (supplying energy to the system) are both methods which can be employed to increase the rate of a reaction." See page 3 of the Advisory Action dated February 4, 2008. The applicant does not agree with this conclusion, particularly since it is unsupported by evidence. Rather, skilled persons know that application of heat and pressure may increase the rate of a reaction depending on the kinetics and thermodynamics of a particular reaction. However, the Examiner has not provided evidence that the kinetics or thermodynamics of the active oxygen step of Schaible et al. would result in an increased reaction rate by application of higher pressure. The contrary may also be true. Schaible et al. does not teach this in regard to

pressure but rather states that a skilled person can ascertain optimum pressure conditions (see page 7, lines 18-23 of Schaible et al.), which could be interpreted to mean that low pressure or vacuum might be advantageous. Further, skilled persons must also consider other potential effects of the use of high pressure such as increased equipment and energy costs, possible effects on the various reactants used in the process, possible effects on any equilibrium reactions, etc. The ultimate effect of using increased pressure is not clear.

ii. Significant, Unexpected Advantage

The applicant has found that the process of the present invention provides a significant, unexpected effect relative to conventional acid hydrolysis processes. Specifically, Example 2 and Table 2 of the present specification demonstrate that it is possible to achieve a significantly lower degree of polymerization (DP) using the process of the present invention (samples 1-5), as compared to control samples 6-11 obtained by conventional acid hydrolysis. Samples 1-5 had DP values consistently lower than comparable samples 6-11 made by conventional acid hydrolysis. None of the cited references teaches or suggests that this additional advantageous effect could be obtained using the process of the present invention. Although Hanna et al. mentions the degree of polymerization ("LODP") at col. 5, line 65 to col. 6 line 9, Hanna et al. suggest that the LODP depends on the LODP of the starting material and does not indicate any dependence on the reaction process or conditions.

Schaible et al. obtains consistently higher DP values than the present invention (e.g. 208-291) though the starting materials are likely different. In any event, the Schaible et al. examples do not appear to provide support for the conclusion that use of an active oxygen compound would permit the process to produce products with a significantly lower degree of polymerization, as in the present invention.

Accordingly, reversal of the Examiner's rejection is requested on the basis that a skilled person would not have a valid reason to combine the references as suggested by the Examiner and because the process of the present invention provides the unexpected benefit of being able to achieve a lower degree of polymerization than conventional acid hydrolysis processes.

B. Claim 9

Claim 9 of the present application is separately patentable on the basis that the Examiner has not shown that the feature of claim 9 is taught or suggested by any of Hanna et al., Schaible et al. or Trusovs. Accordingly, with respect to claim 9, the Examiner has not made out a case of prima facie obviousness since the Examiner has not demonstrated that the feature of claim 9 is taught or suggested by any of the cited prior art.

C. Claim 10

Claim 10 of the present application is separately patentable on the basis that the Examiner has not shown that the feature of claim 10 is taught or suggested by any of Hanna et al., Schaible et al. or Trusovs. Accordingly, with respect to claim 9, the Examiner has not made out a case of prima facie obviousness since the Examiner has not demonstrated that the feature of claim 10 is taught or suggested by any of the cited prior art.

D. Claim 14

Claim 14 of the present application is separately patentable on the basis that the Examiner has not shown that the features of claim 14 requiring that the cellulose material comprises about 30% to about 50% by weight of the reaction mixture, and the hydrogen peroxide comprises about 0.1% to about 10% by weight of the reaction mixture, on a 100% active basis of hydrogen peroxide, are taught or suggested by any of Hanna et al., Schaible et al. or Trusovs. Accordingly, with respect to claim 14, the Examiner has not made out a case of prima facie obviousness since the Examiner has not demonstrated that these features of claim 14 are taught or suggested by any of the cited prior art.

E. Claim 16

Claim 16 of the present application is separately patentable on the basis that the Examiner has not shown that the feature of claim 16 requiring a residence time of 15 minutes or less in the extruder is taught or suggested by any of Hanna et al., Schaible et

al. or Trusovs. Accordingly, with respect to claim 16, the Examiner has not made out a case of prima facie obviousness since the Examiner has not demonstrated that this feature of claim 16 is taught or suggested by any of the cited prior art.

F. Claim 17

Claim 17 of the present application is separately patentable on the basis that the Examiner has not shown that the feature of claim 17 requiring a residence time of 5 minutes or less in the extruder is taught or suggested by any of Hanna et al., Schaible et al. or Trusovs. Accordingly, with respect to claim 17, the Examiner has not made out a case of prima facie obviousness since the Examiner has not demonstrated that this feature of claim 17 is taught or suggested by any of the cited prior art.

3. The Rejection of Claims 18-21, 25-27 and 29-31 Under 35 U.S.C. §103(a)

Claims 18-21, 25-27 and 29-31 stand rejected under 35 U.S.C. §103(a) as unpatentable over the same references and further in view of U.S. Pat. no. 5,192,569 (McGinley). Each of these claims depends from claim 1 and thus the same arguments given above also apply to each of these claims.

McGinley et al. does not cure the defects of the primary references discussed above. Accordingly the same reasons given above apply to the rejection of claims 18-21, 25-27 and 29-31 due to their dependence on claim 1. Reversal of the rejection is requested.

Favorable consideration and reversal of all rejections is requested.

Respectfully submitted,

Date: May 30, 2008

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VIII. Claims Appendix

1. A process for producing microcrystalline cellulose, comprising subjecting to a high shear treatment at elevated temperature, a reaction mixture comprising a cellulose material, an active oxygen compound and water for a time effective to depolymerize the cellulose material.

2. The process of claim 1 wherein the cellulose material is depolymerized to an average degree of polymerization of 400 or less.

3. The process of claim 1 wherein the active oxygen compound is hydrogen peroxide and the reaction mixture is subjected to the high shear treatment in an extruder system including a barrel and a product outlet.

4. The process of claim 3 wherein the elevated temperature during the high shear treatment is at least about 40°C as measured on the barrel.

5. The process of claim 3 wherein the elevated temperature during the high shear treatment is at least about 40°C to 160°C as measured on the barrel.

6. The process of claim 3 wherein the elevated temperature during the high shear treatment is at least about 50°C to 110°C as measured on the barrel.

7. The process of claim 3 wherein the elevated temperature during the high shear treatment is at least about 90°C to 105°C as measured on the barrel.

8. The process of claim 3 wherein pressure at the product outlet is in the range of about 20 to 1500 psi.

9. The process of claim 3 wherein the hydrogen peroxide comprises an aqueous

solution and is admixed with the cellulose material prior to introduction of the cellulose material to the extruder system.

10. The process of claim 3 wherein the hydrogen peroxide comprises an aqueous solution and is introduced into the extruder system after introduction of the cellulose material.

11. The process of claim 9 wherein the cellulose material comprises processed mill pulp, dissolving grade cellulose, purified cellulose, or dry cellulose in sheet or divided form.

12. The process of claim 10 wherein the cellulose material comprises processed mill pulp, dissolving grade cellulose, purified cellulose, or dry cellulose in sheet or divided form.

13. The process of claim 3 wherein the extrusion system comprises a twin screw extruder.

14. The process of claim 3 wherein the extrusion system comprises a twin screw extruder, the cellulose material comprises about 30% to about 50% by weight of the reaction mixture, and the hydrogen peroxide comprises about 0.1% to about 10% by weight of the reaction mixture, on a 100% active basis of hydrogen peroxide.

15. The process of claim 14 wherein the pH of the reaction mixture during extrusion is in the range of about 2 to 8.

16. The process of claim 14 wherein the extrusion is continuous and residence time is 15 minutes or less.

17. The process of claim 14 wherein the extrusion is continuous and residence time is 5 minutes or less.

18. The process of claim 3 wherein the reaction mixture includes an additive added before, during or after the high shear treatment.

19. The process of claim 18 wherein the additive is selected from a cellulose different from the cellulose material, a chemically modified cellulose, a seaweed extract, a natural gum, a protein, a synthetic hydrocolloid, starches, modified starches, dextrins, sugars, surfactants, emulsifiers, salts, and any mixtures of two or more thereof.

20. The process of claim 1 wherein the product is subjected to one or more finishing steps selected from washing, extraction, pH modification, attriting, filtering, screening, and drying to a powder form.

21. The process of claim 1 wherein the finishing steps include washing, attriting to colloidal particle size, and drying to powder form.

22. The microcrystalline cellulose produced by the process of claim 1.

23. The microcrystalline cellulose produced by the process of claim 3.

24. The microcrystalline cellulose produced by the process of claim 14.

25. The microcrystalline cellulose produced by the process of claim 19.

26. The microcrystalline cellulose produced by the process of claim 20.

27. The microcrystalline cellulose produced by the process of claim 21.

28. The process of claim 1 wherein, following the high shear treatment, the reaction mixture is held for a time effective to further depolymerize the cellulose material.

29. The process of claim 20 wherein the finishing step is attriting.

30. The process of claim 29 wherein the material is combined with an additive selected from a cellulose different from the cellulose material, a chemically modified cellulose, a seaweed extract, a natural gum, a protein, a synthetic hydrocolloid, starches, modified starches, dextrins, sugars, surfactants, emulsifiers, salts, and any mixtures of two or more thereof and the combination is attrited.

31. The process of claim 30 wherein the additive is carboxy methyl cellulose.

IX. Evidence Appendix

None

X. Related Proceedings Appendix

None